K023153

Ansell
PROFESSIONAL HEALTHCARE

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NOV 1 3 2002

Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol
Ansell Healthcare Products Inc.
1875 Harsh Avenue SE
Massillon, Ohio 44646
Telephone: 330-833-2811
Fax: 330-833-6501

[1] Summary

[2] Ansell Healthcare Products Inc.
1875 Harsh Avenue SE
Massillon, Ohio 44646

Contact: James R. Chatterton
Telephone: 330-833-2811
Fax: 330-833-6501

September 18, 2002

[3] Trade Name: Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol
Common Name: Examination Gloves
Classification Name: Glove, Patient Examination, Latex

[4] Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol meet all of the requirements of ASTM D 3578-01a$^{\epsilon 2}$.

[5] Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol *meet all the current specifications for* ASTM D 3578-01a$^{\epsilon 2}$ *Rubber Examination Gloves.*

[6] Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol are non-sterile disposable devices intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

[7] Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 3578-01a$^{\epsilon 2}$
Physical Properties	Meets ASTM D 3578-01a$^{\epsilon 2}$
Freedom from holes	Meets ASTM D 3578-01a$^{\epsilon 2}$ Meets ASTM D 5151-99
Powder-Free	Meets ASTM D 3578-01a$^{\epsilon 2}$ Not more than 2 mg residue by mass per glove.

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Biocompatability	
Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes

[8] The performance test data of the non clinical tests are the same as mentioned immediately above.

[9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.

[10] It is concluded that the Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol (Modified) are as safe, as effective, and perform as well as the glove performance standards referenced above and therefore meet:

ASTM listed standards,
FDA hole requirements, and
labeling claims for the product.

[11] This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Mr. James R. Chatterton
Vice President Regulatory
Ansell Healthcare Products, Incorporated
1875 Harsh Avenue, S.E.
Massillon, Ohio 44646-7199

Re: K023153
Trade/Device Name: Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol (Green)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: 80 LYY
Dated: October 25, 2002
Received: October 28, 2002

Dear Mr. Chatterton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

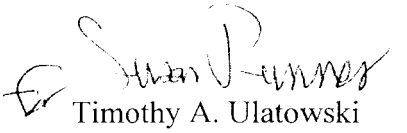
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Number (if known) K023153

Device Name Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol (Green)

Indications for Use Micro-Touch® Next Step™ Powder Free Medical Examination Gloves with Aloe and Glycerol intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023153